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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,824	07/25/2001	William C. Olson	62942-B/JPW/SHS	7125

7590

01/26/2005

John P. White
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New York, NY 10036

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,824	OLSON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,43,46-48 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,43,46-48 and 52-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/912,824

Applicants: Olson, W., and P. J. Maddon

Docket No.: 62942

Filing Date: 07/25/01

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 22 October, 2004. Claims 1, 2, 43, 46-48 were amended and new claims 52-59 introduced. Claims 1, 2, 43, 46-48, and 52-59 are pending in the instant application.

37 C.F.R. § 1.98

The information disclosure statement filed 22 October, 2004, has been placed in the application file and the information referred to therein has been considered.

37 C.F.R. § 1.75(c)

Claims 43 and 48 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claims do **not** refer back in the alternative only, or **refer to a preceding claim**, or reference two sets of claims with different features, or reference another multiple dependent claim. For instance, claim 43 references subsequent claims 52-55 whereas claims 48 references subsequent claims 56-59. Applicant is required to cancel the claim(s), cancel the claim(s) and rewrite the claim(s) in proper dependent form, or amend the claim(s) to place the claims in proper dependent form, or rewrite the claim(s) in independent form. Refer to M.P.E.P. § 608.01(n).

35 U.S.C. § 119(e) and § 120

Applicant's claim for domestic priority under 35 U.S.C. § 119(e) and § 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35

U.S.C. § 112, first paragraph, for claims 52-59, 43, and 48 of this application. The earlier referenced applications **fail** to disclose compositions comprising an admixture containing **T-1249 (SEQ ID NO.: 6)**. Accordingly, for the purposes of applying prior art, the effective filing date for these claims will be that of the instant application (25 July, 2001).

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 43, 46-48, 53, and 57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson et al. (1999) in view of Barney et al. (2001). The claims have been amended to recite a

composition comprising an admixture of Mab PA14 and either peptide T20 or T1249, or Mab PA14, CD4-IgG2, and either peptide T20 or T1249. Olson and colleagues disclose the isolation and characterization of six novel anti-CCR5 Mabs, one of which is designated PA14. This Mab appears to be identical to the antibody currently being claimed. The authors reported that this antibody was capable of inhibiting HIV-1 entry and fusion. This publication also discloses compositions comprising both Mab PA14 and CD4-IgG2. These compounds were also capable of inhibiting viral replication. This teaching does not disclose the peptides T20 or T1249. However, Barney and colleagues provide both peptides T20 and T1249 and indicate that they are potent inhibitors of HIV-1 fusion and entry. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the art-recognized antiviral agents described by Olson et al. (1999) and Barney et al. (2001) into a single composition for the inhibition of HIV-1 replication. The instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*, 205 U.S.P.Q. 1069 (C.C.P.A. 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

Claims 54, 55, 58, and 59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Olson et al. (1999) in view of Barney et al. (2001), as applied *supra* to claims 1, 2, 43, 46-48, 53, and 57, and further in view of Winter (1993). The claims require that the Mab of interest comprise a humanized portion. Winter provides a detailed description of how to make humanized Mabs and identifies the advantages of doing so. Therefore, it would have been *prima*

facie obvious to one having ordinary skill in the art at the time the invention was made to modify Mab PA14 to include humanized portions, since humanized antibodies would reasonably be expected to be less immunogenic and more efficacious than their murine counterparts when administered to a human host.

Claims 43, 48, 52, and 56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trkola et al. (1995) in view of Barney et al. (2001). The claims have been amended to recite a composition comprising an admixture of CD4-IgG2 and either peptide T20 or T1249. Trkola and colleagues disclose the isolation and characterization of a potent antiviral agent consisting of tetrameric CD4-IgG2. This immunological reagent appears to be identical to the fusion protein currently being claimed. The authors reported that CD4-IgG2 was capable of neutralizing different strains of HIV-1. This teaching does not disclose an admixture comprising peptide T20 or T1249. However, Barney and colleagues provide both peptides T20 and T1249 and indicate that they are potent inhibitors of HIV-1 fusion and entry. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the art-recognized antiviral agent described by Trkola et al. (1995) and Barney et al. (2001) into a single composition for the inhibition of HIV-1 replication. The instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*, 205 U.S.P.Q. 1069 (C.C.P.A. 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

Finality of Office Action

Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

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Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

A handwritten signature in black ink, appearing to read 'Jeffrey S. Parkin', with a long horizontal flourish extending to the right.

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

22 January, 2005